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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

TISSUE REGENERATION TECHNOLOGIES, LLC and GENERAL PATENT, LLC, Plaintiffs, v. MALE PERFORMANCE MEDICAL PARTNERSHIP, LLC; MEDICAL PARTNERSHIP, LLC; R. BAXTER TEEGARDEN; LEONARD MESSINA; RICHARD NEISWONGER a/k/a RICK CHARLES; and LAS VEGAS MALE PERFORMANCE CLINIC, Defendants.	Case No.: 2:18-cv-1914-RFB-GWF **AMENDED COMPLAINT**

COME NOW Plaintiffs Tissue Regeneration Technologies, LLC and General Patent, LLC (collectively, "Plaintiffs") file this Amended Complaint against Defendants Male Performance Medical Partnership, LLC, Medical Partnership, LLC, R. Baxter Teegarden, Leonard Messina, Richard Neiswonger a/k/a Rick Charles, and Las Vegas Male Performance Clinic (collectively, "Defendants") and in support hereof show unto the Court the following:

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PARTIES

1. Plaintiff Tissue Regeneration Technologies, LLC ("TRT") is an Ohio limited liability company with its principal place of business located at 251 Heritage Walk, Woodstock, Georgia 30188.

2. Plaintiff General Patent, LLC is a Georgia limited liability company with its principal place of business located at 251 Heritage Walk, Woodstock, Georgia 30188 and consents to venue and jurisdiction in this Court.

3. Defendant Male Performance Medical Partnership, LLC is a Wyoming limited liability company with its principal place of business located at 8329 Slate Harbor Circle, Las Vegas, Nevada 89128 and may be served with Summons and a copy of this Complaint by delivering the same to its principal, Leonard Messina, at 8329 Slate Harbor Circle, Las Vegas, Nevada 89128.

4. Defendant Medical Partnership, LLC is a Wyoming limited liability company with its principal place of business located at 8329 Slate Harbor Circle, Las Vegas, Nevada 89128 and may be served with Summons and a copy of this Complaint by delivering the same to its principal, Leonard Messina, at 8329 Slate Harbor Circle, Las Vegas, Nevada 89128.

5. Defendant R. Baxter Teegarden is a Nevada resident and may be served with Summons and a copy of this Complaint by delivering the same to him personally at his principle place of business located at 2560 E. Sunset Road, Suite 101, Las Vegas, Nevada 89120.

6. Defendant Leonard Messina is a Nevada resident and may be served with Summons and a copy of this Complaint by delivering the same to him personally at 8329 Slate Harbor Circle, Las Vegas, Nevada 89128.

7. Upon information and belief, Defendant Richard Neiswonger a/k/a Rick Charles is a Nevada resident and may be served with Summons and a copy of this Complaint by delivering the same to him personally.

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8. Defendant Las Vegas Male Performance Clinic is an unincorporated partnership and may be served with Summons and a copy of this Complaint by delivering the same to its principal, Leonard Messina, at 8329 Slate Harbor Circle, Las Vegas, Nevada 89128.

JURISDICTION AND VENUE

9. This action arises under the Patent Act, 35 U.S.C. § 101 et seq., including 35 U.S.C. §§ 271, 281, 283, 284, and 285, and the Lanham Act 15 U.S.C. §§ 1051 et seq. Accordingly, this Court has federal question jurisdiction pursuant to 15 U.S.C. § 1121 and 35 U.S.C § 281. This Court has original jurisdiction over this controversy pursuant to 28 U.S.C. §§ 1331 and 1338.

10. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and/or 1400(b).

11. This Court has personal jurisdiction over Defendants. Defendants have minimum contacts within the State of Nevada. Defendants have purposefully availed themselves of the privileges of conducting business in the State of Nevada. Defendants have sought protection and benefit from the laws of the State of Nevada. Defendants regularly and continuously conduct business in Nevada and have infringed or induced infringement, and continue to do so, in Nevada and Plaintiffs' causes of action arise directly from Defendants' business contacts and other activities in the State of Nevada. In addition, this Court has personal jurisdiction over Defendants because minimum contacts have been established with the forum and the exercise of jurisdiction would not offend traditional notions of fair play and substantial justice.

12. Defendants, directly and/or through their intermediaries, ship, distribute, make, use, import, offer for sale, sell, and/or advertise their products and affiliated services in the United States and in the State of Nevada. Moreover, Defendants' website advertises services in this District. See, https://swisscure.org. Defendants have committed patent infringement in the State of Nevada. Defendants solicit customers in the State of Nevada. Defendants have many paying customers who are residents of the State of Nevada and who use Defendants' products in Nevada.

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FACTUAL BACKGROUND

13. This case involves claims of False Advertising under the Lanham Act, 15 U.S.C. §§ 1051 et seq., and patent infringement under the Patent Act, 35 U.S.C. § 101 et seq., based on the advertising, sale and use of Extracorporeal Shock Wave Technology ("ESWT") for various medical indications, specifically Erectile Dysfunction ("ED") and Peyronie's Disease ("PD") with the Storz D-Actor 100 branded as the SwissWave device and the DUOLITH machine (collectively, the "Accused Products").

14. TRT is a medical technology company that develops, manufacturers, and sells ESWT devices used to treat a variety of medical conditions under the name SoftWave™ Acoustic Wave Therapy.

15. General Patent is an affiliate of TRT and is the owner of all patents at issue in this case. General Patent has granted exclusive, world-wide licenses to TRT to use and enforce the patents at issue in this case as necessary for TRT's business.

16. Originally conceived and operated as a research and development company, TRT began marketing and sales operations in 2008.

17. TRT is currently engaged in business throughout the United States. TRT also has a strong international presence through its German affiliate, MTS Europe GmbH.

18. TRT develops and manufactures its "SoftWave" devices through its German affiliate, MTS. The technology utilized in the devices can be categorized into two groups: (a) patented, unfocused "SoftWaves" for soft tissue indications (e.g., wounds) and (b) focused shockwaves for lithotripsy and bony indications (e.g., non-healing fractures).

19. The patented SoftWave technology uses various lens configurations to produce pressure waves. These waves have a characteristic pressure profile of short rise-times reaching high amplitudes (comparable to a sonic boom). The pressure waves can be shaped through a reflector, which enables the transmission of either highly-focused shockwaves for use on urinary stones or non-union fractures, or soft-focused or unfocused pressure waves (*i.e.*, SoftWaves) for most soft tissue indications.

20. Plaintiffs' patented SoftWave technology is distinguished from competitors'

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shockwave technology in that TRT uses a patented parabolic (as opposed to an ellipsoid) reflector in the therapy head. This allows delivery of unfocused waves of acoustic energy over a broad target area.

21. The fact that TRT's SoftWave technology generates less pain, has a higher efficacy rate, and has a lower re-treatment rate further distinguishes it from its competitors' higher-energy, more focused shockwave systems.

22. As the industry leader, TRT's discovery that "soft waves" have the same or better clinical benefit as higher-energy focused shockwaves for most medical conditions has allowed it to further develop the idea into a useful format and secure patents protecting its inventions.

23. TRT's SoftWave technology provides a number of advantageous benefits, including, but not limited to: (a) painless treatments not requiring the use of localized anesthesia; (b) the ability to treat larger surfaces, such as wounds, faster and more efficiently than competing shockwave devices; and (c) small, compact devices that are less expensive to manufacture than competing devices.

24. TRT currently has approval to distribute two devices in the United States: the LithoGold and VetGold systems.

25. General Patent was the first company to discover (and patent the inventions used to generate) the biologic response generated by unfocused SoftWave technology, including: (a) promotion of growth factors (e.g., VEGF, BPM, and OP); (b) promotion of nitric oxide; (c) improved vascularity; and (d) migration and differentiation of stem cells.

26. General Patent's extensive patent portfolio currently includes: (a) twenty-two (22) United States Patents; (b) eight (8) published United States patent applications; (c) two (2) international patent applications; and (d) two (2) international patents. Specifically, the patent portfolio consists of the following:

Patent/Pub. No.	Date	Title
U.S. 7,470,240	Dec. 30, 2008	Pressure pulse/shock wave therapy methods and an apparatus for conducting the therapeutic methods
U.S. 7,841,995	Nov. 30, 2010	Pressure pulse/shock wave therapy methods and an apparatus for conducting the therapeutic methods

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Patent/Pub. No.	Date	Title
U.S. 7,905,845	March 15, 2011	Pressure pulse/shock wave therapy methods and an apparatus for conducting the therapeutic methods
U.S. 7,883,482	Feb. 8, 2011	Pressure pulse/shock wave therapy methods and an apparatus for conducting the therapeutic methods
U.S. 7,507,213	March 24, 2009	Pressure pulse/shock wave therapy methods for organs
U.S. 7,537,572	May 26, 2009	Treatment or pre-treatment for radiation/chemical exposure
U.S. 7,601,127	Oct. 13, 2009	Therapeutic stimulation of genital tissue or reproductive organ of an infertility or impotence diagnosed patient
U.S. 7,497,834	March 3, 2009	Germicidal method for eradicating or preventing the formation of biofilms
U.S. 7,497,835	March 3, 2009	Method of treatment for and prevention of periodontal disease
U.S. 7,544,171	June 9, 2009	Methods for promoting nerve regeneration and neuronal growth and elongation
U.S. 7,600,343	Oct. 13, 2009	Method of stimulating plant growth
U.S. 7,578,796	Aug. 25, 2009	Method of shockwave treating fish and shellfish
U.S. 7,497,836	March 3, 2009	Germicidal method for treating or preventing sinusitis
U.S. 8,162,859	April 24, 2012	Shock Wave Treatment Device and Method of Use
U.S. 7,594,930	Sept. 29, 2009	Method of attaching soft tissue to bone
U.S. 7,988,648	Aug. 2, 2011	Pancreas Regeneration Treatment For Diabetics Using Extracorporeal Acoustic Shock Waves
U.S. 8,257,282	Sept. 4, 2012	Pressure Pulse/Shock Wave Apparatus for Generating Waves Having Plane, Nearly Plane, Convergent Off Target or Divergent Characteristics
U.S. 8,535,249	Sept. 17, 2013	Pressure Pulse/Shock Wave Apparatus for Generating Waves Having Plane, Nearly Plane, Convergent Off Target or Divergent Characteristics
U.S. 7,390,308	June 24, 2008	Apparatus and process for optimized electro-hydraulic pressure pulse generation
U.S. 6,217,531	April 17, 2001	Adjustable electrode and related method
U.S. 7,695,443	April 13, 2010	Device for generating shock waves
U.S. 7,775,995	Aug. 17, 2010	The Use of a Thyristor for Electric Switching During the Generation of Shock Waves
U.S. Pub. 2007/0239082	Oct. 11, 2007	Shock Wave Treatment Device

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Patent/Pub. No.	Date	Title
U.S. Pub. 2008/0191596	Aug. 14, 2008	An Improved Device For Producing Electrical Discharges in an Aqueous Medium
U.S. Pub. 2008/0269651	Oct. 30, 2008	Wound Care Bandaging In Combination With Acoustic Shock Wave Applications
U.S. Pub. 2009/0041864	Feb. 12, 2009	Apparatus and Method for Cellular Extract Enhancement
U.S. Pub. 2009/0088670	April 2, 2009	Shock Wave Coupling Adapter and Method of Use
U.S. Pub. 2009/0093739	April 9, 2009	Apparatus for Generating Electrical Discharge
U.S. Pub. 2011/0177576	June 21, 2011	Shock Wave Cell Treatment Device And Method To Enhance Cell Replication
U.S. Pub. 2008/0183111	June 31, 2008	Device And Method For Generating Shock Waves
EP1981463		Shock Wave Treatment Device And Method Of Use
EP1981412		Improved Shock Wave Treatment Device
WO 2007/098300	Aug. 30, 2007	Shock Wave Treatment Device And Method Of Use
WO 2007/087470	Aug. 2, 2007	Improved Shock Wave Treatment Device

27. Although the individual inventors have assigned their patents and patent applications to General Patent, General Patent has, in return, granted TRT a sole and exclusive, royalty-free, perpetual, and irrevocable license to use and develop all of its patents and patent applications necessary for TRT's business.

28. Specifically, TRT is the exclusive licensee of United States Patent Nos. 8,535,249, entitled *Pressure Pulse/Shockwave Apparatus For Generating Waves Having Plane, Nearly Plane, Convergent Off Target Or Divergent Characteristics*, and 7,841,995 entitled *Pressure Pulse/Shock Wave Therapy Methods And An Apparatus For Conducting The Therapeutic Methods* (collectively, the "Patents-in-Suit") and possesses all right, title, and interest in the Patents-in-Suit, including the right to enforce the Patents-in-Suit, the right to license the Patents-in-Suit, and the right to sue Defendants for infringement and recover past, present and future damages, as described below. The Patents-in-Suit were duly and legally issued by the United States Patent and Trademark Office after full and fair examination.

29. TRT currently has product lines developed for the treatment of five distinct areas of care: (a) CardioGold™ – cardiac and vascular indications; (b) LithoGold™ – lithotripsy and

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urology indications; (c) OrthoGold™ – orthopedic indications; (d) UroGold™ – urology indications; (e) VetGold™ – veterinary indications; and (f) DermaGold™ – wound care indications.

30. Currently, TRT's three primary initiatives consist of: (a) selling approved devices throughout North America; (b) securing legal protection for its products and intellectual property; and (c) obtaining regulatory approval or clearance in the United States.

31. The UroGold 100™ device's compact size and modern design enables it to be transported easily and handled comfortably during treatment.

32. The UroGold 100™ device's versatile and professional applicators enable treatment to be repeated easily and on a regular basis. Therapeutic treatment of urogenital indications with the UroGold 100™ device is uncomplicated to conduct, exceedingly tolerable for the patient, and provides a high degree of satisfaction for both patients and physicians.

33. The UroGold 100™ represents an innovative treatment option that utilizes the biological effects of shock waves by stimulating the self-healing mechanism of the affected tissue on a cellular level. Shock waves promote the generation of new blood vessels and the release of angiogenic growth factors. It has been shown that they also initiate the migration of stem cells and therefore help improve the blood flow in the treated area. In addition, Shock wave-induced revascularization processes can alleviate pain. The combination of all mentioned factors leads to reductions in muscle tension, spasticity, and pain for chronic pelvic pain syndrome ("CPPS").

34. On information and belief, Defendants advertise, market, promote, and license a competing shockwave device by franchising "SwissWave" to doctors and non-doctor owner operators throughout the United States, including in this district.[1]

35. On information and belief, the device used, recommended, promoted, marketed, and sold by Defendants is manufactured by non-party Storz Medical AG, a German company[2], as the Storz D-Actor 100:

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[1] *See* https://us.businessesforsale.com/us/franchises/opportunities/swiss-wave-business.
[2] *See* https://www.karlstorz.com/de/en/world-company.htm?d=CORP.

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36. On information and belief, Defendants advertise, promote, and market the Storz D-Actor 100 branded as the SwissWave device as an ED and PD treatment to patients, doctors, and non-doctor franchisees throughout the United States and Canada, including patients, doctors, and non-doctor franchisees in this District.

37. On information and belief, Defendants also advertise, promote, market and sell its DUOLITH SD1 device for the treatment of, among other things, erectile dysfunction (ED).

38. On information and belief, Defendants train doctors and non-doctor franchisees to the use of the Storz D-Actor 100 and/or the DUOLITH devices, one or more of which arebranded as the SwissWave device to treat ED and PD patients throughout the United States and Canada, including patients in this District.

39. Plaintiffs are engaged in commerce within the control of Congress.

40. Defendants' devices and services compete directly with those of Plaintiffs.

COUNT I

Violations of the Lanham Act, 15 U.S.C. § 1125

41. Plaintiffs re-allege and incorporate by express reference the preceding Paragraphs as if fully restated and set forth herein.

42. Defendants claim that "[i]ndependent published research papers have proven [the] safety and efficacy" of treating ED with the Accused Products, one or more of which are branded as the SwissWave device.

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43. Defendants' websites contain links to the following purported "Case Studies:"[3]

Article	Date	Journal	Author
Men's Power-Pressure Wave Erectile Regeneration-Therapy: an Early Assessment	April 10, 2017	Urology & Nephrology Open Access Journal	Perelman, Jason
Low Intensity Extracorporeal Shockwave Therapy for Erectile Dysfunction: A Study in an Indian Population	Feb. 2015	The Canadian Journal of Urology	Srini, Vasan Satya
Low-Intensity Extracorporeal Shock Wave Therapy—A Novel Effective Treatment for Erectile Dysfunction in Severe ED Patients Who Respond Poorly to PDE5 Inhibitor Therapy	2012	Journal of Sexual Medicine	Gruenwald, Ilan
Does Low Intensity Extracorporeal Shock Wave Therapy Have a Physiological Effect on Erectile Function? Short-Term Results of a Randomized, Double-Blind, Sham Controlled Study	May 2012	The Journal of Urology	Vardi, Yoram
Evaluation of clinical efficacy, safety and patient satisfaction rate after low-intensity extracorporeal shockwave therapy for the treatment of male erectile dysfunction: an Australian first open-label single-arm prospective clinical trial	2015	BJUI	Chung, Eric
Evaluation of clinical efficacy, safety and patient satisfaction rate after low-intensity extracorporeal shockwave therapy for the treatment of male erectile dysfunction: an Australian first open-label single-arm prospective clinical trial	2015	BJUI	Chung, Eric
Penile Low-Intensity Shock Wave Therapy: A Promising Novel Modality for Erectile Dysfunction	April 2014	Korean Journal of Urology	Abu-Ghanem, Yasmin

[3] *See* http://swisscure.org/about-us/. A copy of the "About Us" page from Defendants' website printed on July 30, 2018 at 2:59 PM is attached hereto as **Exhibit A** and incorporated herein by express reference.

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Article	Date	Journal	Author
Shockwave treatment of erectile dysfunction	2013	Therapeutic Advances in Urology –	Gruenwald, Ilan
Low-Intensity Shock Wave Therapy and Its Application to Erectile Dysfunction	Dec. 31, 2013	Work Journal of Men's Health	Lei, Hongen
Can low-intensity extracorporeal shockwave therapy improve erectile dysfunction? A prospective, randomized, double-blind, placebo controlled study	Oct. 4, 2016	Scandinavian Journal of Urology	Olsen, Anne. B.
Low-intensity Extracorporeal Shock Wave Treatment Improves Erectile Function: A Systematic Review and Meta-analysis	May 31, 2016	European Urology	vLu, Zhihua
A curative therapy for ED edges forward	Oct. 1, 2015	Urology Times	Burnett, Arthur, II

44. Only one (1) of the eleven (11) purported "Case Studies" linked on Defendants' websites involves a Storz D-Actor 100.

45. Three (3) of the ten (11) purported "Case Studies" link to abstracts (Srini 2015, Gruenwald 2012, and Vardi 2012) rather than the full text article.

46. One (1) of the purported "Case Studies" linked to Defendant's website consists of editorial comment and contains no clinical research (Burnett 2015).

47. Of the seven (7) full text "Case Studies," four (4) merely review prior literature (Abu-Ghanem 2014, Gruenwald 2013, Lei 2013, and Lu 2016) and contain no independent findings of their own.

48. Only three (3) of the purported "Case Studies" contain actual independent clinical analysis (Perelman 2017, Chung 2015, and Olsen 2016). None of these "Case Studies," however, supports Defendant's assertion that the "safety and efficacy" of LESWT to treat ED has been "proven." In fact, Chung concludes that "further basic research is required to explore the various pathophysiological mechanisms of LiESWT on erectile tissue including long-term efficacy, safety, and histological changes." Olsen concludes similarly that "[t]he effect of LI-EWST on erectile dysfunction has not been clearly determined." Lastly, Perelman acknowledges that "to date no long term follow up" has been performed.

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49. As part of their advertising campaign to promote the use of the Storz D-Actor 100 branded as the SwissWave device to treat ED, Defendants have made and continue to make statements regarding their products and/or services including, but not limited to, the following:

(a) "Independent published research papers have proven its safety and efficacy with 86% of men saying they would recommend it to a friend."[4]

(b) "SwissWave Protocol is a scientifically ***proven*** procedure that uses pulsed-wave energy to improve sexual performance." (Emphasis added).[5]

(c) "[W]e want to provide you with the safest, yet most effective treatments to improve your condition. SwissWave Protocol accomplishes both of these goals for our male patients seeking improved sexual performance."[6]

(d) "The SwissWave is an evidence-based, alternative treatment for erectile dysfunction, or ED."[7]

(e) "SwissWave Protocol has ***proven*** to be a safe and effective drug-free, surgery-free alternative to Viagra and other oral ED medications. In fact, SwissWave Protocol has been shown to be **TWICE** as effective as Viagra and similar ED drugs, without any of the harmful side effects!"[8]

(f) "SwissWave Protocol has been shown to be a drug-free, surgery-free way to break down the scar tissue and reduce the curvature of the penis typical of Peyronie's Disease."[9]

(g) "You need to be aware that this very expensive device has tried to be copied by the Chinese and several others. WHY ARE WE TELLING YOU THIS? The answer is simple – the knock-off machines don't work. In order of this treatment to have

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[4] *Id.*
[5] *See* http:// swisscure.org/services/. A copy of the "Services" page from Defendant's website printed on July 6, 2018 at 3:52 PM is attached hereto as **Exhibit B** and incorporated herein by express reference.
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*

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the desired effect on erectile tissue the WAVE MUST BE FOCUSED to one millimeter. Think about it. We are trying to stimulate a very specific area in the penis. If the wave is not perfectly calibrated the treatment won't be effective."[10]

(h) "[C]linically-proven SwissWave treatment."[11]

(i) "FDA registered for soft tissue repair which increases blood flow to the penis."[12]

(j) "The FDA cleared the therapy for use in the United States for soft tissue repair, kidney stone intervention, and to increase blood flow, including in the treatment of ED."[13]

(k) "[T]he medical device used in this extremely effective approach has been cleared by the FDA for the repair of soft tissue and improved blood circulation and is being used throughout the world."[14]

(l) "A double-blind study published in the journal, *Therapeutic Advances in Urology*, found that acoustic wave therapy delivered a significant clinical improvement of erectile function without any adverse effects."[15]

(m) "An article in *Urology Times* … concluded that acoustic wave therapy has been tested extensively through randomized, placebo-controlled, and open-label studies in clinics worldwide. It concluded that the technology had demonstrated 'impressive efficacy and safety.'"[16]

(n) "[A recent study published in *Journal of Sexual Medicine* found **that every single man in the study** treated with acoustic pressure waves showed improvement in erectile function."[17]

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[10] *See* http://swisscure.org/. A copy of the "Home" page from Defendant's website printed on July 6, 2018 at 3:53 PM is attached hereto as **Exhibit C** and incorporated herein by express reference.
[11] *See* https://us.businessesforsale.com/us/franchises/opportunities/swiss-wave-business.
[12] *Id.*
[13] *See* https://www.peakhealthlife.com/services/swisswave-protocol.
[14] *See* http://swisscure.org/medical-times-today/.
[15] *Id.*
[16] *Id.*
[17] *Id.* (Emphasis in original).

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(o) "In fact, a full 30 percent of men in the study who were using oral ED medication achieved significant improvement—and didn't need to use medication for months after receiving acoustic pressure wave treatment."[18]

(p) "The Protocol … has been tested and used successfully for years…."[19]

(q) "[T]he SwissWave Protocol offers a proven treatment for ED that's painless, long lasting, and successful—with no side effects."[20]

(r) Independent published research papers have proven its safety and efficacy…."[21]

50. Defendants' representations regarding their products and/or services constitute commercial speech for the purpose of influencing consumers to pay for their services.

51. Defendants supply the information regarding SwissWave products and services for local providers to post on their websites.[22]

52. Defendants' representations regarding their products and/or services propose commercial transactions.

53. Defendants' representations regarding their products and/or services appear in paid advertisements on the internet.

54. Defendants' representations regarding their products and/or services are false and misleading.

55. Defendants' representations regarding their products and/or services have deceived, or have the capacity to deceive, consumers, including consumers in this District.

56. Defendants' deceptive and/or false representations regarding their products and/or services have, and will continue to have, a material effect on consumers' purchasing decisions, including the purchasing decisions of consumers in this District.

57. By claiming the "safety and efficacy" of treating ED with the Accused Product(s)

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[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *See* https://sunmedllc.com; https://fla-medicalgroup.com; http://alphamedicalgroup.com/; https://txmedicalcenter.com; https://arcmenshealth.com.

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branded as the SwissWave device is "***proven***," Defendants have misrepresented and continue to misrepresent an inherent quality or characteristic of their product and/or service.

58. By claiming treating ED with the Accused Product(s) branded as the SwissWave device as "***clinically-proven***," Defendants have misrepresented and continue to misrepresent an inherent quality or characteristic of their product and/or service.

59. By claiming the "safety and efficacy" of treating ED with the Accused Product(s) branded as the SwissWave device is "***proven***" by "[independent[ly] published research papers," Defendants have misrepresented and continue to misrepresent an inherent quality or characteristic of their product and/or service.

60. By claiming "SwissWave Protocol uses a Swiss-made medical device cleared by the Food and Drug Administration (FDA)," Defendants have misrepresented and continue to misrepresent an inherent quality or characteristic of their product and/or service.

61. By claiming "[t]he FDA cleared the therapy for use in the United States for soft tissue repair … and to increase blood flow, including in the treatment of ED," Defendants have misrepresented and continue to misrepresent an inherent quality or characteristic of their product and/or service.

62. By claiming the Accused Product(s)branded as the SwissWave device is "FDA registered for soft tissue repair which increases blood flow to the penis," Defendants have misrepresented and continue to misrepresent an inherent quality or characteristic of their product and/or service.

63. By claiming the Accused Product(s) branded as the SwissWave device provides benefits to men with and without ED, Defendants have misrepresented and continue to misrepresent an inherent quality or characteristic of their product and/or service.

64. By claiming the Accused Product(s) branded as the SwissWave device breaks down and/or reduces scar tissue associated with PD, Defendants have misrepresented and continue to misrepresent an inherent quality or characteristic of their product and/or service.

65. By claiming treatment with the with the Accused Product(s) branded as the SwissWave device grows, repairs, and/or expands blood vessels, Defendants have misrepresented

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and continue to misrepresent an inherent quality or characteristic of their product and/or service.

66. Defendants' deceptive and/or false misrepresentations regarding the Accused Product(s) branded as the SwissWave device and the treatment of ED and PD therewith affect interstate commerce.

67. Plaintiffs have been injured and will continue to be injured as a direct and proximate result of Defendants' deceptive and/or false representations regarding their products and/or services. Consumers are more likely to seek a treatment for ED and/or PD that is "proven," "FDA approved," and/or supported by "[i]ndependent[ly] published research papers" than one that is not.

68. Defendants have damaged the reputation of TRT's product by, among other things, representing their inferior Accused Product(s) branded as the SwissWave device as being equal or superior to Plaintiffs' product.

69. Plaintiffs' position in the marketplace has been damaged by Defendants' false and/or deceptive advertising.

70. By publishing false and misleading representations regarding their products and/or services on the internet, Defendants have disseminated sufficiently said statements to the relevant purchasing public so as to constitute advertising or promotion within the ED and PD treatment market.

71. Defendants' representations regarding their products and/or services are used for promotional purposes to persuade consumers in the market for alternative ED and PD treatments to use the SwissWave product and/or service.

72. Defendants' representations regarding their products and/or services refer to SwissWave as a specific product and/or service.

73. Defendants have an economic motivation for making false and deceptive representations regarding their products and/or services. Specifically, Defendants know that representing the SwissWave product and/or service as, among other things, "proven," "FDA approved," and/or supported by "[i]ndependent[ly] published research papers" will induce consumers to seek out their services.

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74. As a direct and proximate result of Defendants' actions, Plaintiffs have been injured by lost sales, loss of good will, and damage to their business reputation.

75. Plaintiffs are entitled to an award of (a) profits earned by the Defendants falsely or misleadingly representing the (i) nature, (ii) characteristics, and/or (iii) qualities of SwissWave; (b) the damages sustained by Plaintiffs as a result of each Defendant's wrongful acts, and (c) the costs of this action pursuant to 15 U.S.C. § 1117.

76. The Defendants will continue to make false or misleading representations of fact regarding the nature, characteristics, and/or qualities of SwissWave, causing irreparable harm to Plaintiff for which there is no adequate remedy at law, unless enjoined by this Court as provided by 15 U.S.C. § 1116.

COUNT II

Patent Infringement (U.S. Patent No. 8,535,249)

77. Plaintiffs re-allege and incorporate by express reference the preceding Paragraphs as if fully restated and set forth herein.

78. United States Patent No. 8,535,249 (hereinafter, the "'249 Patent") was duly and legally issued by the USPTO on September 17, 2013 to its inventors, Walter Uebelacker, Reiner Schultheiss, Wolfgang Schaden, and John Warlick, and was initially assigned to General Patent, LLC.[23]

79. The '249 Patent recites claims directed to an apparatus for generating pressure pulse/shock waves to produce a tissue reaction in a subject to which the wave is administered and wherein the waves have a power density in the range of approximately 0.01 mJ/mm2 up to 1.0 mJ/mm2 to stimulate living tissue and avoiding tissue damage.

80. Defendants have infringed and continue to infringe the '249 Patent, either literally or under the doctrine of equivalents, through the promotion, advertising, commercial development, branding, and sales of infringing products. Upon information and belief, each of

[23] A true and accurate copy of the '249 Patent is attached hereto as **Exhibit D** and incorporated herein by express reference.

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the Defendants has infringed and continues to infringe one or more claims of the '249 Patent, including at least Claims 1 and 20 (the "'249 Patent Claims") because they promote, distribute, make, use, import, offer for sale, sell, and/or advertise the Accused Products. Specifically, the Defendants have infringed the '249 Patent by making, using, promoting, selling, offering for sale, and/or importing into the United States devices claimed and disclosed in the '249 Claims.[24]

81. Each of the Defendants has intentionally induced and continues to induce infringement of the '249 Patent Claims in this district and elsewhere in the United States, by their intentional acts which have successfully, among other things, encouraged, instructed, enabled, and otherwise caused others to use the Accused Products in an infringing manner. Despite knowledge of the '249 Patent as early as the date of service of this Complaint, Defendants continue to encourage, instruct, enable, and otherwise cause their customers to use devices claimed in the '249 Patent claims.[25] The provision of and sale of the Accused Products provides Defendants with a source of revenue and business focus. Each of the Defendants has specifically intended its customers to use the Accused Products in such a way that infringes the '249 Patent. Each of the Defendants knew that its actions, including but not limited to, making the Accused Products available for sale under their trade name would induce, has induced, and will continue to induce infringement by their vendors and customers by continuing to sell, support, and instruct said customers on using the Accused Products.

82. Defendants' aforesaid activities have been without authority and/or license from Plaintiffs.

83. Plaintiffs are entitled to recover from each of the Defendants the damages sustained by Plaintiffs as a result of each Defendant's wrongful acts in an amount subject to proof

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[24] See **Exhibit E** attached hereto and incorporated herein by express reference.

[25] See *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1345 (Fed. Cir. 2012); see also *Soteria Encryption, LLC v. Lenovo United States, Inc.*, Case No. CV 16-7958-GW(JPRx), 2017 WL 3449058, *2 (C.D. Cal. Feb. 27, 2017) ("courts have held that post-suit knowledge is sufficient to sustain a finding that defendant had the requisite knowledge to support claims for induced infringement."); *Labyrinth Optical Technologies, LLC v. Fujitsu America, Inc.*, Case No. SACV 13-0030 AG (MLGx), 2013 WL 12126111 (C.D. Cal. Aug. 201, 2013) ("The Federal Circuit therefore held that knowledge of the asserted patent from a complaint in the same case is sufficient to meet the knowledge requirement of indirect infringement.").

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at trial, said amount not being less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

84. Defendants' infringement of Plaintiffs' rights under the '249 Patent will continue to damage Plaintiffs, causing irreparable harm to Plaintiffs for which there is no adequate remedy at law, unless enjoined by this Court.

COUNT III

Patent Infringement (U.S. Patent No. 8,535,249)

Against Las Vegas Male Performance Clinic

85. Plaintiffs re-allege and incorporate by express reference the preceding Paragraphs as if fully restated and set forth herein.

86. The medical provider immunity from suit provided by 35 U.S.C. § 287(c), does not exempt medical providers from being sued for using devices which infringe on device patents.[26]

87. Defendant Las Vegas Male Performance Clinic is using the Accused Product(s) branded as the SwissWave device, which infringes the '249 Patent.

88. Defendant Las Vegas Male Performance Clinic is involved in the commercial development of demand for the Accused Product(s) through its advertising and marketing efforts using the SwissWave trade name and branded marketing materials. Defendant Las Vegas Male Performance Clinic's aforesaid activities have been without authority and/or license from Plaintiffs.

89. Plaintiffs are entitled to recover from Defendant Las Vegas Male Performance Clinic the damages sustained by Plaintiffs as a result of each of said Defendant's wrongful acts in an amount subject to proof at trial, said amount not being less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

90. Defendant Las Vegas Male Performance Clinic's infringement of Plaintiffs' rights under the '249 Patent will continue to damage Plaintiffs, causing irreparable harm to Plaintiffs

[26] *Emtel, Inc. v. Lipidlabs, Inc.*, 583 F.Supp.2d 811 (E.D. Tex. Sept. 20, 2008)

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for which there is no adequate remedy at law, unless enjoined by this Court.

COUNT IV

Patent Infringement (U.S. Patent No. 7,841,995)

91. Plaintiffs re-allege and incorporate by express reference the preceding Paragraphs as if fully restated and set forth herein.

92. United States Patent No. 7,841,995 (hereinafter, the "'995 Patent") was duly and legally issued by the USPTO on October 13, 2009 to its inventors, Reiner Schultheiss, Wolfgang Schaden, and John Warlick, and was initially assigned to General Patent, LLC.[27]

93. The '995 Patent recites claims relating to the field of treating mammals with acoustic pressure pulse shock waves, generally, and more specifically, to treating various conditions found in humans and animals using shockwaves that are generated as either focused waves at high or low energy levels or non-focused waves at preferably low energy levels or a combination of such waves.

94. The claims of the '995 Patent are directed to a method of stimulating a substance that is tissue having cells, which can be an organ of a mammal, including a human. Such organ may include the skin or any other organ. The tissue may be, inter alia, muscle or tendon and may be part of (a) the vascular system, (b) the nervous system, (c) the urinary systems, (d) the nervous system, (e) the lymph node, or (f) pituitary system.

95. Defendants promote, market, and grant licenses to their physician customers and non-doctor franchisees to independently provide a procedure under the trade name SwissWave to patients that incorporates Plaintiffs' patented methods to treat ED and PD, among other things. Like the '995 Patent, "SwissWave Protocol uses pulsed-energy waves to open and repair blood vessels and increase blood flow to [the] penis."[28]

96. Defendants' marketing efforts include providing instructional materials to third-party medical providers and non-doctor franchisees on how to practice the patented methods.

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[27] A true and accurate copy of the '995 Patent is attached hereto as **Exhibit F** and incorporated herein by express reference.

[28] *See* http://swisscure.org/

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Defendants make these instructional materials available throughout the country, including to interested medical providers, and non-doctor franchisees, and patients in this District.

97. Defendants promise to provide (a) medical support as well as (b) branding, marketing, and business development services to third-party medical providers and non-doctor franchisees.

98. Defendants charge new franchisees $99,700 for a 95 percent ownership interest in the clinic. As such, Defendants retain 5 percent ownership in all franchise clinics. Defendants are also paid 5 percent of the net profit from each franchise clinic on a monthly basis. In exchange for the franchise fee, Defendants "provide[] the SwissWave equipment and computer, the physician's Doppler ultrasound and extensive intellectual properly, include[ing] but not limited to all advertising materials, appointment, staff and discharge scripts, extensive clinic forms, the complete business operating system and the exclusive territory."

99. Defendants have infringed and continue to infringe the '995 Patent, either literally or under the doctrine of equivalents, by promoting, marketing, training, and licensing the use of infringing methods. Specifically, each of the Defendants has infringed and continues to infringe one or more claims of the '995 Patent, including at least Claims 1 and 3 (the "'995 Patent Claims") by: (a) promoting, marketing, and advertising the SwissWave Protocol to potential customers who are both medical providers and non-doctor franchisees; (b) licensing the SwissWave Protocol to their medical provider and non-doctor franchisees; (c) training their medical provider and non-doctor owner operator customers to provide the SwissWave Protocol; and (d) providing marketing and advertising support to their medical provider and non-doctor franchisees to create awareness and demand by patients for the SwissWave Protocol. As such, the Defendants have infringed the '995 Patent by utilizing the methods claimed and disclosed in the '995 Claims.[29]

100. Each of the Defendants has intentionally induced and continues to induce infringement of the '995 Patent Claims in this district and elsewhere in the United States, by their intentional acts which have successfully, among other things, encouraged, instructed, enabled,

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and otherwise caused others to use the SwissWave Protocol in an infringing manner. Despite knowledge of the '995 Patent as early as the date of service of this Complaint, Defendants continue to encourage, instruct, enable, and otherwise cause their customers to use their systems and methods, in a manner which infringes the '995 Patent claims.[30] The provisioning and licensing of the SwissWave Protocol provides Defendants with a source of revenue and business focus. Each of the Defendants has specifically intended their customers to use the SwissWave Protocol in such a way that infringes the '995 Patent. Each of the Defendants knew that their actions, including but not limited to, making the SwissWave Protocol available for license and sale under their trade name would induce, has induced, and will continue to induce infringement by their customers by continuing to promote, advertise, train, support, and instruct said customers on using the SwissWave Protocol.[31]

101. Defendants' aforesaid activities have been without authority and/or license from Plaintiffs.

102. Plaintiffs are entitled to recover from Defendants the damages sustained by Plaintiffs as a result of each of the Defendants' wrongful acts in an amount subject to proof at trial, said amount not being less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

103. Defendants' infringement of Plaintiff's rights under the '995 Patent will continue to damage Plaintiff, causing irreparable harm to Plaintiff for which there is no adequate remedy at law, unless enjoined by this Court.

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[30] See *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1345 (Fed. Cir. 2012); see also *Soteria Encryption, LLC v. Lenovo United States, Inc.*, Case No. CV 16-7958-GW(JPRx), 2017 WL 3449058, *2 (C.D. Cal. Feb. 27, 2017) ("courts have held that post-suit knowledge is sufficient to sustain a finding that defendant had the requisite knowledge to support claims for induced infringement."); *Labyrinth Optical Technologies, LLC v. Fujitsu America, Inc.*, Case No. SACV 13-0030 AG (MLGx), 2013 WL 12126111 (C.D. Cal. Aug. 201, 2013) ("The Federal Circuit therefore held that knowledge of the asserted patent from a complaint in the same case is sufficient to meet the knowledge requirement of indirect infringement.").

[31] See **Exhibit G** attached hereto and incorporated herein by express reference.

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COUNT V

Patent Infringement (U.S. Patent No. 7,841,995)

Against Las Vegas Male Performance Clinic

104. Plaintiffs re-allege and incorporate by express reference the preceding Paragraphs as if fully restated and set forth herein.

105. The medical provider immunity from suit provided by 35 U.S.C. § 287(c), does not exempt medical providers from being sued who are engaged in the commercial development of a device or procedure.[32]

106. Defendant Las Vegas Male Performance Clinic is involved in the commercial development of the SwissWave branded device and procedure through their advertising and marketing efforts using the SwissWave trade name and branded marketing materials. Defendant Las Vegas Male Performance Clinic's aforesaid activities have been without authority and/or license from Plaintiffs.

107. Plaintiffs are entitled to recover from Defendant Las Vegas Male Performance Clinic the damages sustained by Plaintiffs as a result of each of said Defendant's wrongful acts in an amount subject to proof at trial, said amount not being less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

108. Defendant Las Vegas Male Performance Clinic's infringement of Plaintiffs' rights under the '995 Patent will continue to damage Plaintiffs, causing irreparable harm to Plaintiffs for which there is no adequate remedy at law, unless enjoined by this Court.

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[32] *Viveve, Inc. v. Thermigen, LLC*, 2:16-CV-1189-JRG, 2017 WL 1425604 (E.D. Tex. Sept. 20, 2017).

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JURY DEMAND

109. Plaintiffs demand a trial by jury on all issues.

WHEREFORE Plaintiffs Tissue Regeneration Technologies, LLC and General Patent LLC pray upon this Court for the following relief:

(a) That summons issue and Defendants be served according to law;

(b) That Plaintiffs recover from Defendants all past and future damages caused by their violations of the Lanham Act and patent infringement;

(c) That Plaintiffs recover an award of profits earned by the Defendants, actual damages sustained by Plaintiffs and the costs of this action pursuant to 15 U.S.C. § 1117;

(d) A grant of permanent injunction pursuant to 15 U.S.C. § 1116 enjoining Defendants and their respective officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise, from further use of false and/or misleading advertising regarding the nature, characteristics and/or qualities of SwissWave;

(e) An adjudication that one or more claims of the Patents-in-Suit has been infringed, either literally and/or under the doctrine of equivalents, by one or more of the Defendants;

(f) An adjudication that one or more of the Defendants has induced infringement of one or more claims of the Patents-in-Suit;

(g) An award of damages to be paid by Defendants adequate to compensate Plaintiffs for Defendants' past infringement and any continuing or future infringement up until the date such judgment is entered, including interest, costs, and disbursements as justified under 35 U.S.C. § 284 and, if necessary to adequately compensate Plaintiffs for Defendants' infringement, an accounting of all infringing sales including, but not limited to, those sales not presented at trial;

(h) A grant of permanent injunction pursuant to 35 U.S.C. § 283, enjoining Defendants and their respective officers, agents, servants, employees, and attorneys, and

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those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise, from further acts of infringement with respect to any one or more of the claims of the Patents-in-Suit;

(i) That this Court declare this to be an exceptional case and award Plaintiffs their reasonable attorneys' fees and costs in accordance with 35 U.S.C. § 285; and

(j) Any such other and further relief deemed just and proper by this Court.

Dated this 17th day of May 2019.

WEIDE & MILLER, LTD.

By: */s/ F. Christopher Austin*

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